

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ÉTATS-UNIS D'AMÉRIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 16 July 2001 (16.07.01)	Applicant's or agent's file reference BMID 9916PCT
International application No. PCT/US00/25631	Priority date (day/month/year) 20 September 1999 (20.09.99)
International filing date (day/month/year) 19 September 2000 (19.09.00)	
Applicant BUCK, Harvey, B. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
11 April 2001 (11.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer F. Baechler Telephone No.: (41-22) 338.83.38
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

12

Applicant's or agent's file reference BMID 9916PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/25631	International filing date (day/month/year) 19/09/2000	Priority date (day/month/year) 20/09/1999
International Patent Classification (IPC) or national classification and IPC C12Q1/00		
Applicant ROCHE DIAGNOSTICS CORPORATION et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 11/04/2001	Date of completion of this report 10.01.2002
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Leber, T Telephone No. +49 89 2399 7195



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/25631

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-22 as originally filed

Claims, No.:

1-27 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/25631

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-27.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-27 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/25631

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 1 and 23 refer to a "sensor comprising a volume of a hydrophilic medium". Such medium could, for example be, water, a buffered aqueous solution or glass beads. The said hydrophilic medium serves to retain an amount of analyte "proportionate" to the concentration of the analyte in the biological fluid assayed. As the sensor encompasses already a hydrophilic medium such as water, any addition of a sample from a biological fluid will unavoidably lead to a dilution of the said biological fluid and the analytes therein. It is therefore unclear (Art 6 PCT), how the feature of "proportionate" can be maintained. Moreover, claims 1 and 23 suggest that the biological fluid is "in contact with the sensor". The technical meaning of this is unclear (Art 6 PCT) as there is an "enclosure for said analyte retention volume", indicating that there is no exchange between the "hydrophilic medium" containing the "retention volume" and the "biological fluid" in contact with the sensor.

In addition, claims 2 and 10 refer to the method of claim 1 wherein the interval between the intermittent applied potentials is "less" (claim 2) or "equal or greater" (claim 10) than the time necessary for the concentration of the analyte in the retention volume to equilibrate with that in the biological fluid in contact with the sensor. For such an equilibration to take place, an exchange of material between the sample inside the enclosure and the fluid outside must take place. This, however, appears to go against claim 1 which refers to an "enclosure" suggesting that no material exchange takes place. According to the description the enclosure may encompass an "analyte permeable membrane" (page 6, lines 24-27). This feature, which is missing in claims 1 and 23, appears suitable to overcome some of the objections raised above. The description, however, also states that "such a membrane is not necessary to the operation of the sensor and as such is not required" (page 6, lines 24-27). Thus, the description appears not to provide information to overcome said contradictions.
2. In conclusion, claims 1, 2, 10 and 23 and the claims dependent thereon are so unclear (Art 6 PCT) that no meaningful opinion regarding novelty, inventive step and industrial applicability can be formed (Art 34(4)(a)(ii) PCT).

Re Item VII

Certain defects in the international application

1. The expression "herein incorporated by reference" or equivalents thereof (e.g. page 8, lines 1 and 27) in the description of the present application should have been deleted (Guidelines, Section IV, II-4.17).
2. The vague and imprecise statement in the description of the present application (page 22, lines 2-4) implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Art. 6 PCT) when used to interpret them (Guidelines, Section IV, III-4.3a). The statement should therefore have been amended to remove this inconsistency.

Re Item VIII

Certain observations on the international application

1. The term "substantially" in claim 1 lacks clarity (Art 6 PCT).
2. The meaning of "initially predetermined" in claim 1 lacks clarity (Art 6 PCT).
3. The term "PQQ" in claims 4 and 27 lacks clarity (Art 6 PCT).
4. The phrase "...applied mediator oxidizing applied ..." in claim 1 lacks clarity (Art 6 PCT).
5. Claim 10 lacks clarity (Art 6 PCT) as it is unclear what the term "interval" refers to. It appears that a defining phrase such as "between the intermittent applied potentials" used in claim 2 is missing.

(19) World Intellectual Property Organization
International Bureau



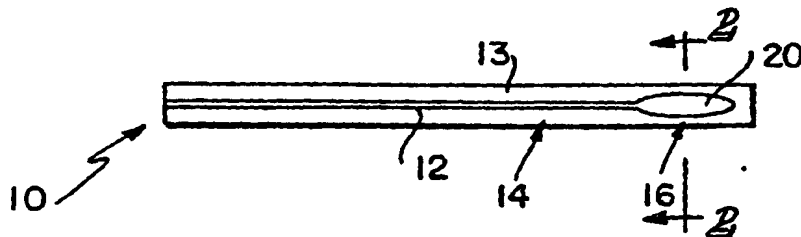
(43) International Publication Date
29 March 2001 (29.03.2001)

PCT

(10) International Publication Number
WO 01/21827 A1

- (51) International Patent Classification⁷: C12Q 1/00 (74) Agent: WOODBURN, Jill, L.; The Law Office of Jill L. Woodburn, L.L.C., 6633 Old Stonehouse Dr., Newburgh, IN 47630 (US).
- (21) International Application Number: PCT/US00/25631
- (22) International Filing Date:
19 September 2000 (19.09.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/154,731 20 September 1999 (20.09.1999) US
- (71) Applicants (for all designated States except US):
ROCHE DIAGNOSTICS CORPORATION [US/US];
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- (72) Inventors; and
- (75) Inventors/Applicants (for US only): BUCK, Harvey, B.
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(US). ESSENPREIS, Matthias [DE/US]; 38775 Stoning-
ton Terrace, Fremont, CA 94536 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— With international search report.
— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SMALL VOLUME BIOSENSOR FOR CONTINUOUS ANALYTE MONITORING



(57) Abstract: Sensors (10, 110, 210, 310, 410) and a method for detecting an analyte are described. Sensors (10, 110, 210, 310, 410) each have a volume of a hydrophilic medium (24) that retains an amount of analyte proportionate to the concentration of analyte in a biological fluid, electrodes (12) and a redox

enzyme in contact with medium (24), and an electron transfer mediator. The fluid contacts sensors (10, 110, 210, 310, 410) and at initially predetermined intervals intermittently applies a potential to electrode (12) sufficient to oxidize the mediator and sensing current through electrode (12) as a function of the duration of the applied potential. The applied mediator oxidizing applied potential is maintained for a period of time sufficient to determine the rate of change of current with time through electrode (12). The current flow is correlated with the current flow for known concentrations of the analyte in medium (24).

WO 01/21827 A1

INTERNATIONAL SEARCH REPORT

Int. . onal Application No

PCT 00/25631

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 35225 A (TOMASCO MICHAEL F ;HELLER ADAM (US); HELLER E & CO (US); SAY JAMES) 13 August 1998 (1998-08-13)	1-6, 10-17,21
Y	abstract	23-27
	page 12, line 30 -page 13, line 8	
	page 37, line 3 - line 8	
	page 40 -page 41; example 3	
	page 42, line 18 - line 21	
	page 46 -page 51; claims	
	1,8,11-26,33,36,41-45	
	page 56 -page 58; claims 82,89-94	
A	figure 10	7-9, 18-20
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

19 February 2001

Date of mailing of the international search report

27/02/2001

Name and mailing address of the ISA

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Authorized officer

Tuynman, A

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/25631

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 29199 A (BIO MERIEUX ; GARNIER FRANCIS (FR)) 2 November 1995 (1995-11-02) figures 2A,3 page 11; example 1 page 13, line 26 -page 14, line 2	23-27
A	WO 93 06237 A (ALLAGE ASSOCIATES INC) 1 April 1993 (1993-04-01) page 28 -page 29; claims 1-5 page 12, line 30 -page 14, line 28	1,7-10, 16-21
A	WO 98 58250 A (ELAN CORP PLC) 23 December 1998 (1998-12-23) page 14, line 14 -page 15, line 26 page 24, line 1 -page 25, line 6	1,2, 7-10, 16-21
A	US 5 735 273 A (KURNIK RONALD T ET AL) 7 April 1998 (1998-04-07) column 16, line 10 -column 17, line 27	7-10, 16-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/25631

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9835225 A	13-08-1998	AU 6157898 A EP 0958495 A JP 2000509507 T US 6143164 A US 6120676 A	26-08-1998 24-11-1999 25-07-2000 07-11-2000 19-09-2000
WO 9529199 A	02-11-1995	FR 2720832 A CA 2165978 A EP 0705291 A JP 9504334 T US 6096825 A	08-12-1995 02-11-1995 10-04-1996 28-04-1997 01-08-2000
WO 9306237 A	01-04-1993	US 5312762 A	17-05-1994
WO 9858250 A	23-12-1998	IE 970443 A AU 8031898 A EP 0990151 A TW 380046 B ZA 9805189 A	16-12-1998 04-01-1999 05-04-2000 21-01-2000 08-01-1999
US 5735273 A	07-04-1998	AU 703849 B AU 6497396 A CA 2229509 A EP 0876501 A JP 11512316 T WO 9710356 A US 6141573 A US 5827183 A	01-04-1999 01-04-1997 20-03-1997 11-11-1998 26-10-1999 20-03-1997 31-10-2000 27-10-1998

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference BMID 9916PCT	FOR FURTHER ACTION		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US 00/ 25631	International filing date (day/month/year) 19/09/2000	(Earliest) Priority Date (day/month/year) 20/09/1999	
Applicant ROCHE DIAGNOSTICS CORPORATION et al.			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

SMALL VOLUME BIOSENSOR FOR CONTINUOUS ANALYTE MONITORING

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

/US 00/25631

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12Q1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 35225 A (TOMASCO MICHAEL F ;HELLER ADAM (US); HELLER E & CO (US); SAY JAMES) 13 August 1998 (1998-08-13)	1-6, 10-17,21
Y	abstract page 12, line 30 -page 13, line 8 page 37, line 3 - line 8 page 40 -page 41; example 3 page 42, line 18 - line 21 page 46 -page 51; claims 1,8,11-26,33,36,41-45 page 56 -page 58; claims 82,89-94 figure 10	23-27
A	--- -/--	7-9, 18-20

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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

19 February 2001

Date of mailing of the international search report

27/02/2001

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Tuynman, A

INTERNATIONAL SEARCH REPORT

International Application No

/US 00/25631

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 29199 A (BIO MERIEUX ;GARNIER FRANCIS (FR)) 2 November 1995 (1995-11-02) figures 2A,3 page 11; example 1 page 13, line 26 -page 14, line 2 ----	23-27
A	WO 93 06237 A (ALLAGE ASSOCIATES INC) 1 April 1993 (1993-04-01) page 28 -page 29; claims 1-5 page 12, line 30 -page 14, line 28 ----	1,7-10, 16-21
A	WO 98 58250 A (ELAN CORP PLC) 23 December 1998 (1998-12-23) page 14, line 14 -page 15, line 26 page 24, line 1 -page 25, line 6 ----	1,2, 7-10, 16-21
A	US 5 735 273 A (KURNIK RONALD T ET AL) 7 April 1998 (1998-04-07) column 16, line 10 -column 17, line 27 -----	7-10, 16-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

/US 00/25631

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9835225	A	13-08-1998	AU 6157898 A EP 0958495 A JP 2000509507 T US 6143164 A US 6120676 A	26-08-1998 24-11-1999 25-07-2000 07-11-2000 19-09-2000
WO 9529199	A	02-11-1995	FR 2720832 A CA 2165978 A EP 0705291 A JP 9504334 T US 6096825 A	08-12-1995 02-11-1995 10-04-1996 28-04-1997 01-08-2000
WO 9306237	A	01-04-1993	US 5312762 A	17-05-1994
WO 9858250	A	23-12-1998	IE 970443 A AU 8031898 A EP 0990151 A TW 380046 B ZA 9805189 A	16-12-1998 04-01-1999 05-04-2000 21-01-2000 08-01-1999
US 5735273	A	07-04-1998	AU 703849 B AU 6497396 A CA 2229509 A EP 0876501 A JP 11512316 T WO 9710356 A US 6141573 A US 5827183 A	01-04-1999 01-04-1997 20-03-1997 11-11-1998 26-10-1999 20-03-1997 31-10-2000 27-10-1998